

## Food and Drug Administration, HHS

## §522.311

(ii) *Indications for use.* For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations.* Do not use in horses intended for human consumption.

[72 FR 27957, May 18, 2007, as amended at 73 FR 31358, June 2, 2008; 74 FR 61516, Nov. 25, 2009; 75 FR 22524, Apr. 29, 2010]

### § 522.275 N-Butylscopolammonium bromide.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) N-butylscopolammonium bromide.

(b) *Sponsor.* See No. 000010 in §510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* 0.3 mg per kilogram of body weight (0.14 mg per pound) slowly intravenously.

(2) *Indications for use.* For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 35512, June 25, 2004]

### § 522.300 Carfentanil citrate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 3 milligrams of carfentanil citrate.

(b) *Sponsor.* See No. 053923 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 to 20 micrograms per kilogram (.005 to .020 milligram per kilogram) of body weight.

(2) *Indications for use.* For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations.* Inject into large muscle of neck, shoulder, back, or hindquarter. Avoid intrathoracic, intra-abdominal, or subcutaneous injection. To reverse effect, use 7 milligrams of diprenorphine for each milligram of carefentanil citrate, given intravenously or one-half intravenously and one-half intramuscularly or subcutaneously. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Do not use in animals that display clinical signs of severe cardiovascular or respiratory disease. Available data

are inadequate to recommend use in pregnant animals. Avoid use during breeding season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[53 FR 40057, Oct. 13, 1988. Redesignated at 73 FR 29685, May 22, 2008]

### § 522.304 Carprofen.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) carprofen.

(b) *Sponsor.* See No. 000069 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003. Redesignated at 73 FR 29685, May 22, 2008]

### § 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 000069 in §510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 3.6 mg/pound (lb) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and

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wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount*. Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

[73 FR 29685, May 22, 2008]

### § 522.313 Ceftiofur injectable dosage forms.

#### § 522.313a Ceftiofur crystalline free acid.

(a) *Specifications*. The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 mg ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Swine*. The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount*. 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. For the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, *H. parasuis*, and *S. suis* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations*. Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required.

(2) *Cattle*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. 6.6 mg ceftiofur equivalents per kg of body weight as a single injection. For subcutaneous injection in the middle third of the posterior aspect of the ear or in the posterior as-

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pect of the ear where it attaches to the head (base of the ear) in beef and non-lactating dairy cattle. For subcutaneous injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levis* in beef, non-lactating dairy, and lactating dairy cattle.

(iii) *Limitations*. Following label use as a single treatment, a 13-day pre-slaughter withdrawal period is required. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

(3) *Horses*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use*. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations*. Do not use in horses intended for human consumption.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004. Redesignated and amended at 71 FR 39546, July 13, 2006; 73 FR 58872, Oct. 8, 2008; 75 FR 4692, Jan. 29, 2010; 75 FR 62468, Oct. 12, 2010]

#### § 522.313b Ceftiofur hydrochloride.

(a) *Specifications*. Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.